

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

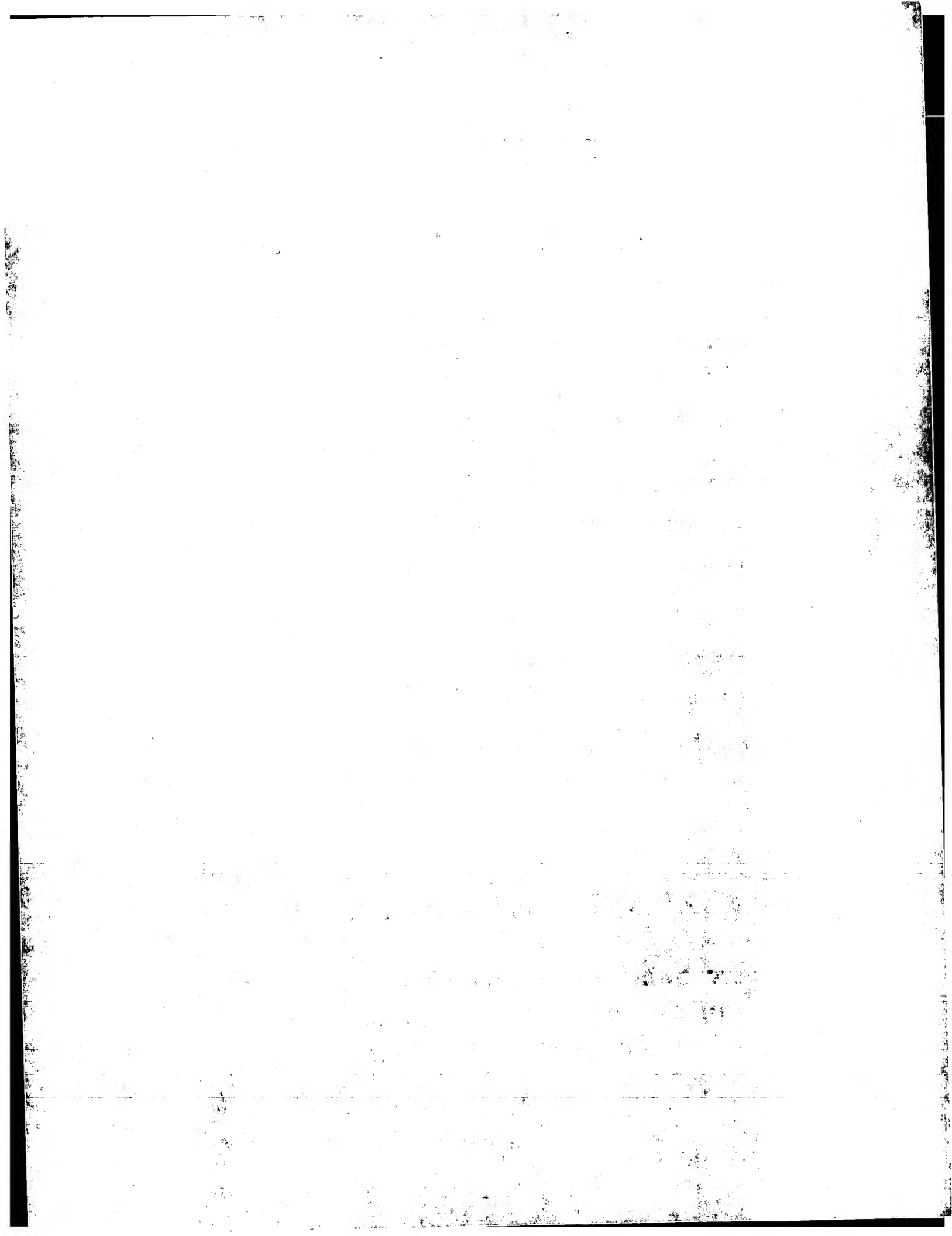
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 September 2001 (27.09.2001)

PCT

(10) International Publication Number
WO 01/71636 A2

(51) International Patent Classification⁷: G06F 19/00

(21) International Application Number: PCT/IB01/00417

(22) International Filing Date: 20 March 2001 (20.03.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/535,433 23 March 2000 (23.03.2000) US

(71) Applicant: MITSUBISHI CHEMICAL CORPORATION [JP/JP]; 5-2 Marunouchi, 2-chome, Chiyoda-ku, Tokyo 100-0005 (JP).

(72) Inventor: O'YOUNG, Lionel; 575 Seastorm Drive, Redwood City, CA 94065 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 01/71636 A2

(54) Title: PERSONALIZED HEALTH PROFILING SYSTEM AND METHOD

(57) Abstract: A system and method of allowing an individual to gain detailed information which is representative in part of their own personalized state of health or well being is disclosed. More specifically, in one aspect the present invention provides for collecting data representative of one or more physiological characteristics of an individual over time. The data can be temporarily or permanently stored in a collection device or sensor. The data is transmitted to a computer environment which includes an analysis site configured at least in part for analyzing the data and producing results representative of the one or more physiological characteristics.

PERSONALIZED HEALTH PROFILING SYSTEM AND METHODField of the Invention

5 This invention relates generally to the field of healthcare and medical information and services, and more particularly to a personalized system and method for an individual to obtain or profile information representative of the individual's state of health. Moreover, this information can be shared and/or distributed to the relevant medical and/or healthcare professional at the individuals' direction.

Background of the Invention

15 The medical community continues to face significant challenges. With the aging of populations, such as the United States population, usage of our medical resources is rising. Costs associated with medical care have also continued to rise even with the advent of managed care systems such as health maintenance organizations (HMOs). Doctors and other medical professionals are under increasing pressure to see more patients and to spend less time on each one.

20 In recent years, the focus on preventative medicine has increased as employers and patients look at ways of controlling health care costs, and increasing the quality of life. People, and Americans in particular, have become more health conscious over the years. There has been a proliferation of health clubs, health stores, medical self help books, alternative medicine services, and the like.

25 While people have become more concerned and aware of their health, it is become increasingly difficult to obtain time with one's doctor or other medical professional. Yet it would be very valuable for an individual to be able to obtain a sense of one's health that is more in depth than just one's general feeling of well being. For example, early detection of certain diseases would be extremely valuable. Yet with the increase of managed care, it is increasingly difficult for an individual to obtain personalized, early medical testing when they do not have a specific complaint or specific health risk factors. Monitoring of one's state of health via the medical system is also difficult.

35 There have been attempts to provide for obtaining information about one's health outside of the doctor's office or hospital. The focus of such systems however, have been limited to monitoring for known health conditions. Further, the

focus on medical monitoring has been on monitoring directed by a doctor, such as for example, as described in U.S. Patent No. 4,531,527 which provides for an ambulatory monitoring system or as described in U.S. Patent No. 5,974,124 which is directed by a medical practitioner. All of these prior art references are directed to monitoring and/or doctor supervised monitoring of patients. More recent patents focus on computerized diagnosis which employ computer algorithms that based on answers to detailed questions provide a score to determine a disease diagnosis, such as that described in US Patent No. 6,022,315. This technique does not put the individual in control of information, or data collection, regarding their own health state, but instead is limited to a method of for diagnosing a disease. It would be highly desirable to provide a system and method that provides for individually direction, collection, analysis, and/or monitoring of data representative of one's state of health.

15

Summary of the Invention

The inventors have discovered a system and method that allows an individual to gain detailed information which is representative in part of their own personalized state of health or well being. This information can be collected and/or analyzed on a continuous or periodic basis to allow for monitoring of the information. This allows for an individual to collect and/or analyze the information at any time and anywhere. The invention provides for self generated medical data and charts representative of ones physiological data. The present invention allows for early detection of warning signs of potential disease, or a change in one's state of health or physical state. The present invention gives individuals a powerful tool which provides objective health data representative of certain physiological characteristics.

25

These and other object and advantages are provide by the system and method of the present invention wherein a method of providing information regarding the health of individuals is provided. Providing information is used broadly herein and includes, but is not limited to collecting, analyzing and/or monitoring (collectively referred to as profiling) information. The method of the present invention generally comprises the steps of: collecting data representative of one or more physiological

30

characteristics of an individual over a period of time. The data can be temporarily or permanently stored in the collection device(s). Then this data will be transmitted to a "computer environment" directly or via any other electronic data transmission-enabling media, such as the internet, telephone lines, and the like. The computer
5 environment includes an analysis site having a primary computer which is configured at least in part for analyzing the data and producing one or more desired analytical results representative of the one or more physiological characteristics. The desired analytical results are then outputted to the individual and to any third party authorized by the individual.

10 Of particular advantage, the present invention allows for the individual to select the desired type or mode of processing and/or the form of the desired analytical results. This feature allows the individual to "personalize" the analyzing of the data and the results provided to him or her. For example, the individual may select desired analytical results that provide a graphical representation of the data,
15 such as heart rate readings. Alternatively, the individual may select a comparison of heart rate readings collected over two or more periods of time. Or the individual may select statistical information, such as information pertaining to how many times certain readings exceeded a selected threshold value, or the standard deviation of the data, and the like.

20 In another aspect of the present invention, a system is provided comprising broadly a sensor coupled to a computer environment. The sensor is worn proximate the body of the individual for collecting data representative of one or more physiological characteristics of the individual, and the sensor has storage and at least one output. The computer environment has an input and storage and is configured
25 to receive the data from the sensor and to analyze the data to produce one or more analytical results selected by the individual.

In another embodiment, the computer environment includes a primary computer, an Internet server connected to the primary computer, a computer network, and one or more remote sites connected to the Internet server via the
30 computer network.

Brief Description of the Drawings

Other objects and advantages of the present invention will become apparent upon reading the detailed description of the invention and the appended claims provided below, and upon reference to the drawings, in which:

5 Fig. 1 is a block diagram illustrating the personalized health profiling system of the present invention.

Fig. 2 is a schematic diagram illustrating the configuration of a computer network according to one embodiment of the system of the present invention.

10 Figs. 3a and 3b are flow charts depicting the personalized health profiling method according to two embodiments of the present invention.

Fig. 4 shows a plot of fluctuations in a persons stride interval or gait.

Fig. 5 illustrates a set of raw gait data collected during an individual's walking, i.e. the signal of pressure changes during walking.

15 Fig. 6 is a schematic diagram depicting the system of the present invention according to one embodiment.

Fig. 7 depicts one graphical representation of the data showing data points representative of an individuals physiological characteristics over time.

Fig. 8 is another graphical representation of physiological characteristics data for a plurality of individuals plotted over time.

20 Fig. 9 is a another graphical representation showing normalized physiological characteristics data over time.

Fig. 10 is another graphical representation of normalized data over a period of time which shows a sudden downward slope of the line indicating a deterioration in an individual's health state.

25 Figs. 11a and 11b show the heartbeat signals for a normal heart and a diseased heart, respectively.

Fig. 12 is an example of one form of the analytical results of the heartbeat signals for Figs. 11a and 11b, where line 1 corresponds to the signal of Fig. 11a and line 2 corresponds to the signal of Fig. 11b.

Detailed Description of the Invention

The present invention herein provides a personalized health system and method which allows one or more individuals to independently collect data regarding certain physiological characteristic of that individual, and to download
5 this data in a computer environment. The data is then processed, such as by statistical analysis and any other sort of profiling or processing techniques, to provide desired analytical results to the individual that are representative of their physiological characteristics, or physical or health state. The individual may also provide access to their individual data or analytical results to others, such as their
10 doctor, hospital, insurance company, or other health care professional, and the like (collectively called "third parties"). Of particular advantage, the system and method of the present invention provides for the individual to select the desired analytical result and to direct its display in any desired form, thereby putting one's own detailed physiological data in the hands of that individual, which previously was
15 only originally accessible to the medical community. This data, and its processed or profiled form, may be sent, preferably via the computer environment, to third parties authorized by the individual, such as to a doctor for medical analysis.

Of particular advantage, the method of the present invention provides for what is termed herein as "timeless" data collection representative of one's health
20 state. The terms "health state" or "physical state" as used herein means the individuals' physiological data or characteristics. In other words, the term health state or physical state are representative of one's overall health as measured by their physiological data or characteristics. Timeless data collection means that the data collection is conducted during the individual's normal daily life or activity, as
25 described in greater detail below. An individual's normal daily life or activity is considered as their normal routine and the activities the individual engages in, such as working, exercising, dinning, sleeping, traveling, and the like. The common aspect to all of these activities, is that data collection is performed during one's regular or normal activities and does not require special or separate activity to
30 perform data collection. This provides great advantages, and opens up the field of health monitoring or data collection to many people. In contrast, the prior art techniques have been limited to persons with expensive specialized equipment

and/or require special monitoring sites, such as for those who are already ill and are being closely monitored in a hospital environment. Further these prior art techniques are limited to persons who are already ill with known conditions and do not offer data collection, analysis and/or monitoring to the general public.

5 In general the system and method of the present invention are illustrated in Fig. 1, a simplified block diagram of one embodiment of the present invention. In Fig. 1 a personalized health profiling (PHP) system 100 is shown. As a system the invention comprises computer hardware and software. In general the system is comprised of data collection means 120, data input/output means 140, and analysis
10 site 110. Data, representative of one or more of an individual's physiological characteristics is collected via the data collection means 120. Preferably, raw data is collected by a sensor 122, that is the data points or signals are collected and stored in storage 124 without processing. The data is then transferred or downloaded from the data collection means to the data input means 140. Data input means 140 is
15 preferably a computer environment, and in particular a remote computer 150 having input/output storage means 160 for receiving and storing the data transferred from the data collection means.

 The analysis site 110 is preferably a computer environment, and in particular is a primary computer, and is configured to receive data, to analyze or
20 process data and to output a desired analytical result, as described in further detail below. The analysis site also includes output means to output or communicate that result to the individual. Further, the desired analytical result may be output or communicated to third parties 170 as authorized by the individual. Examples of
25 third parties that might be authorized by an individual include, but are not limited to, doctors, hospitals, insurers, research institutes, health maintenance organizations, other medical professionals, and the like.

 In an alternative embodiment, the data can be inputted directly to the analysis site. For example, when the analysis site is the World Wide Web accessible via the Internet, a Web page is accessed and the individual can directly
30 key in the information, as opposed to storing and downloading data from the data collection means. Alternatively, the data can be input either manually or automatically to the remote computer 150 which then communicates with the

analysis site 110 via a computer network. Or in a completely remote or self-contained embodiment, the analytical software can be installed in the personal computer which the individual has the responsibility of maintaining the data as well as the analytical software.

5 Of significant advantage, the analysis site 110 is configured to analyze and to produce or display a desired result which is responsive to a selection by the individual. For example, the individual may select various graphical representations of the data. Alternatively, the individual may select that the data be sorted by day of the week, or time of day, and the like, to show variations in their physiological
10 characteristics throughout the day or week. Techniques may be employed to show trends in the data over time. For example, an individual may wish to monitor the progress of a new exercise program, and in particular to determine if their heart rate is stronger over time which can be an indication of increased physical fitness. It yet another embodiment of the present invention, the analysis site may be configured,
15 responsive to an individual's selection, to provide statistical information pertaining to the data, such as for example how many time a data reading exceeds a selected threshold value, or standard deviation information. Thus, the analysis site is configurable to produce many types of analytical results and display of the data, including but not limited to those just described as examples, and all may be
20 implemented by known software programming techniques by those of ordinary skill in the art. Further examples of processing or analytical techniques that the analysis site may be configured to, include but are not limited to, general statistical analysis, Fast Fourier Transformation (FFT), time series analysis based on known techniques such as Detrended Fluctuation Analysis (DFA), Wavelet analysis, Fractal analysis,
25 Multi-fractal analysis, and the like.

 The desired analytical result may be output by the analysis site by any suitable means. Preferably, the analytical result is output to the remote computer
150 wherein the individual may access and store the results on the remote computer 150. Alternatively, the results may be printed from the analysis site and then a hard
30 copy of the desired analytical results are sent to the individual and/or authorized third parties. It should be understood that the description given for input and output to and from the analysis site for an individual is the same as for the authorized third

parties.

A key aspect of the invention is the data collection. Of particular advantage, the present invention preferably provides for "timeless" data collection. Preferably, the sensor is a small device that collects data in a non-obtrusive and noninvasive manner. The sensor is worn by the individual proximate to their body. The sensor may be worn in a continuous manner, or alternatively may be worn periodically. In other words, the sensor may be worn during any and all activities, and during one's normal activity such as walking, jogging, exercising, working, driving, sleeping, and the like. The type of sensor worn will be determined by the type of physiological characteristic to be measured. The placement of the sensor on the body will also be determined by the type of physiological characteristic to be measured. The sensor is a device that does not substantially interrupt the individuals normal daily life or activity, and thus are preferably compact, light, portable and/or wearable.

The type of sensors suitable for use in the system and method of the present invention depend on which type of signal or physiological characteristics is to be detected. To measure and/or monitor an individual's heart beat, examples of such suitable sensors include, but are not limited to the following devices described in Japanese Patent No. 1981914 by Matsushita Electric Industrial Co., Ltd., a blue-light LED sensor used in Pulse Graph developed by Seiko Corporation; and devices described in Japanese Patent Application No. Toku 10-349748.

Japanese Patent No. 1981914, the entire disclosure of which is hereby incorporated by reference herein, describes a device that transmits a light through the fingertip and then receives the signals with a photo detector. The intensity difference between the light transmission and the received signals corresponds to the flow rate and intensity of the blood. This information can then be converted into the moment of the heartbeat.

Another example of a sensor suitable for use in the present invention is a device made by Seiko which also transmits a blue light through a fingertip and then receives the signals with a photo detector. This intensity change can be correlated to the changes of the hemoglobin concentration.

Yet another example of a sensor device suitable for practice with the system and method of the present invention is a noninvasive device for determining

physiological parameters in the blood as described in US Patent No. 5,978,691, the entire disclosure of which is hereby incorporated by reference herein. The device described in the '691 patent may be used to determine blood gases, pH, hemoglobin levels and oxygen content in the blood. As described, the device may be worn by an individual, preferably on a finger and measures such data by inducing temperature changes in the blood. To be employed with the present invention, the device will be equipped with storage means for storing the data collected and output means for transmitting the stored data.

Another suitable sensor is a gait rhythm measurement device described in Japanese Patent Application No. Toku 10-349748 assigned to Mitsubishi Chemical Corporation, the entire disclosure of which is hereby incorporated by reference herein. The device is a compact strain type acceleration sensor that is attached to a person's waist. The sensor detects the pressure changes and the frequency in the acceleration and deceleration during the person's walking rhythm. It has been proposed by Hausdorff, Jeffrey, et al. in Altered fractal dynamics of gait: reduced stride-interval correlations with aging and Huntington's disease, Journal of Applied Physiology, Vol. 82, No.1, pp. 262-269, January 1997, that one's gait, and changes in their gait, is representative of one's overall health state, and more specifically that stride-interval correlations would be altered by changes in neurological function associated with aging and certain disease states. In experiments conducted by Hausdorff the sensor device is a small recording device strapped to a person's ankle that records signals generated from force-sensitive resistors placed inside the shoes of the person. The analog force generated when the person's foot strikes the ground is sampled at 300 Hz with a 12 bit A/D converter, and recorded using a microcomputer that is worn around the person's ankle. Thus, this available device may be employed with the system and method of the present invention to collect data representative of that person's gait over a period of time (t). Once collected the data is transmitted to the analysis site via a remote computer or directly, and the desired analysis and desired analytical result of such data is selected by the individual.

Thus, as illustrated by the above examples, many types and variations of sensors and devices may be employed with the method of the present invention to

collect data representative of an individual's one or more physiological characteristics or data. The type and nature of the sensor or device is not limited, and the only requirements according to the system and method of the present invention is that the sensor or device measure a physiological characteristic or parameter, is suitable for wearing during one's daily activity, has storage means for storing the data, and may be read or downloaded or has output means for transmitting the data to another source. Preferably, the sensor or device will be compact and noninvasive.

In another embodiment of the present invention, a sensor may be employed which is capable of providing certain amount of analysis of the data. In other words, in one embodiment the sensor is configured to locally perform a certain amount of the analysis. Additionally, the sensor may optionally be equipped with a preferably small or compact display. Typically the sensor is capable of performing much less analysis than the analysis site is capable of. The type of analysis performed by the sensor will generally not require much storage but is programmable or configured to process the data as it is collected and to display a simple representation of the data such as its average value. For example the sensor could include a wrist band with a digital display similar to a digital watch, which could display the individual's average heart beat. Of course as the technology develops, and more functions may be performed by small sensor devices, then such devices will be suitable for practice with the system and method of the present invention.

Thus, the sensor can simply store data with no analysis, or the sensor can be configured to provide a certain amount analysis of the data. Since the analysis provided by the sensor is limited, and will not show long term trends or periodic abnormalities in the data, it is always preferred that the data collected by the sensor be transmitted to the analysis site for complete processing. Further, unlike with the sensor, large amounts of data may be stored at the analysis site which is periodically backed up, and thus the data will not be lost.

Data pertaining to a wide variety of physiological characteristics may be collected and/or monitored according to the system and method of the present invention. In general, the physiological characteristics may be subconscious or

involuntary function of the body, or the physiological characteristics may be conscious or voluntary functions. Examples of such physiological characteristics include but are not limited to: rate of the heartbeat, frequency and/or amplitude of the heartbeat, blood pressure, body temperature, blood parameters including oxygen content, eye movements, breathing, and voluntary characteristics such as gait, tapping of fingers or feet, and the like.

To provide for analysis of the data, the system of the invention is now described. The analysis site 110 includes hardware and software configured for any suitable analysis of the data. One embodiment of the computer hardware configuration of the system of the present invention is shown in Fig. 2. Preferably, the system 100 is implemented through software executed on the analysis site. The analysis site includes a primary or host computer connected to computer network 200 and may include a website that organizes content, such as directing the analytical processing of the data and selection of desired analytical results. More specifically, Fig. 2 shows the analysis site 110. The analysis site 110 may include one or more computers, and preferably includes a primary or host computer 210 connected via a line 212 to an Internet server 220. The line 212 may be any suitable connection such as a direct connection, a modem, wireless connection, and further can be a private network such as a local area network (LAN), or other intranet.

The Internet server 220 is connected, preferably via a high speed multi-line telephone interface 222 to a computer network 200. The computer network 200 is preferably the World Wide Web (Internet) computer network, and to one or more remote sites 140. The remote sites are operated by the individuals or authorized third parties. The remote sites are typically remote desktop computers 150 (as shown) that are connected to the network 200 via modems 226 and telephone lines 228. The remote sites 140 may also be comprised of other forms of computers such as workstations, laptop computers, palm tops, dumb terminals, another computer network, or any other computer capable of communicating with other computers. Other suitable connections may be used such as a direct connection, wireless connection, wired connectors such as a modem and a T1 line, or a high speed data line such as a digital subscriber line (DSL). The computers may be a conventional

design, utilizing a central processing unit (CPU) 240 and various memory and supporting circuitry. Connected to the processor 240 is a keyboard 242, and monitor 244. One or more external memory devices 246, such as but not limited to a floppy drive, hard disk drive, PC memory card, zip drive, CD-ROM drive, CD-Rewritable drive, DVD drive, and the like may also be incorporated in the computer, and may be used for downloading and/or storing the data collected from the sensor. Data is transmitted between the sensor and the remote computer and between the remote computer and the analysis site by any suitable communications means. For example, modems may be used and data is transmitted over the telephony network. Alternatively, a digital subscriber line (DSL) may be used. In yet another embodiment, a wireless transmission may be made. In an even further embodiment, the data may be stored on an external memory device which is delivered or mailed directly to the analysis site or to an authorized third party.

In order to transfer the data to the analysis site, data synchronization techniques may be used. For example with the sensor or device, in addition to the necessary units for transmitting and measuring the signal, the sensor will also preferably contain memory and storage units that will collect the new data measurements, i.e. the new data after the last data synchronization with the analysis site. The storage unit itself may be similar to a hard disk of a computer that will be used to save data in the event of a dead battery.

In a preferred embodiment, data transmission to the analysis site, or from the sensor to the remote computer, is wireless. Thus, when the data is transferred either directly to the analysis site or directly to an authorized third party location such as the doctor's office, the data transfer is configured to the industry standard wireless application protocol (WAP). WAP is currently used by Code Division Multiple Access Systems (CDMA) and by companies such as Phone.com and Palm. Using this protocol, the data can be transmitted in the latest wireless data transfer technology. Of course, we are not limiting to wireless transfer only, and the user may transfer the data via physical connections as described above. Also it is important to note, as will be recognized by those of ordinary skill in the art, the data transfer may be configured to other industry protocols that are currently available and that become available in the future. For data transmission, data synchronization

is used. Preferably, fast and efficient data synchronization is used, such as that provided by the Palm Autosynchronization feature. Data synchronization is used at the analysis site or anywhere that the analysis will be carried out, in order to synchronize the data being sent from the sensor to the system database.

5 Residing within the analysis site is the processing means for analyzing the data. The processing means is comprised of software configured to process and/or analyze the data responsive to the selection made by the individual or authorized third party. Many different types of analysis may be performed. For example the analysis site may be configured by known programming methods to provide the
10 following, but not limited to, analytical techniques: general statistical analysis, Fast Fourier Transformation (FFT), time series analysis based on known techniques such as Detrended Fluctuation Analysis (DFA), Wavelet analysis, Fractal and Multi-fractal analysis, and the like. To begin the data analysis, the individual or authorized third party selects the type or mode of analysis of the data by selecting a
15 certain desired analytical result. The analytical results may be communicated to the individual or authorized third party in a variety of ways. In one example, the individual may interface with the analysis site via a website. The content and arrangement of the website may vary greatly, but in general will include, but is not limited to, a home page where overview information is provided. The home page
20 will include a plurality of links. For example, the links may provide access to the analysis site, or may send the individual to a Doctor's website, or other health information website. In an illustrative embodiment, a link is included which, when selected, begins the data transfer sequence and preferably provides the individual with information for carrying out the transfer of data collected by the sensors to the
25 analysis site for processing.

 In another example, the individual or authorized third party may communicate via facsimile or phone. In this example, the desired analytical result(s) are requested via phone or facsimile and the information may be provided in written form and mailed or faxed. Alternatively, the results may be
30 communicated over the phone.

 Two embodiments of the method of the present invention are illustrated in Figs. 3a and 3b. Specifically, the method is broadly shown in Fig. 3a, wherein

beginning at step 300 the individual collects data representative of that individual's physiological characteristics. The data collected is then inputted into the computer environment at step 310. The data is analyzed at step 320 and the desired analytical result as selected by the individual is outputted to the individual or authorized third parties at step 330.

Another embodiment of the method of the present invention is illustrated in Fig. 3b. In this embodiment, the computer environment is the Internet computer network and the analysis site including a website. Specifically, the method comprises the following steps. Beginning with step 400, the individual registers with or subscribes to the analysis site. The individual may also authorize the registration or subscription of third parties to the analysis site in step 410. Upon registration, the individual receives the sensor or device for collecting the data in step 420. The individual then collects data representative of one or more of their physiological characteristics in step 430. The data may be collected continuously, or periodically, for a desired period of time. There is no limitation on the period of time for data collection, and any period of time desired by the individual is suitable. For analysis to show trends in the data and for statistical analysis, longer periods of time are preferred, such as weeks or months. Further, some individuals may wish to collect data for an indefinite period of time, to provide for monitoring of one's physiological characteristics, such as heart rate or blood pressure.

Once collected, a query is made to determine the locale for processing in step 440. If the data is to be analyzed or processed at the analysis site, the data is downloaded or inputted to the analysis site via a computer as described above. Alternatively, an individual may prefer to perform the analysis locally, that is at their own computer (i.e. the remote computer). In this case, the appropriate software is downloaded from the analysis site to the remote computer in step 500. The individual selects the type of mode of analysis of the data in step 510 and the analysis is performed at the remote computer in step 520. Once the analysis is complete, the desired results are displayed to the individual on their remote computer in step 530.

In the embodiment where the data is input to the analysis site, the individual next selects the type or mode of analysis of the data in step 450. As described

above, many types of analysis may be performed on the data. The data is analyzed responsive to the selection in step 460, and the desired analytical results are output to the individual and to authorized third parties as directed by the individual in step 470.

5

EXAMPLES

The following examples are provided to show the many ways in which the system and method of the present invention may be used to obtain information regarding an individual's health or physical state as represented by a variety of their physiological characteristics. The examples are provided for illustration purposes only, and are not to limit the scope of the invention in any way.

This example is related to the usage of gait rhythm. As described above, it has been proposed by Hausdorff, et al. that an individual's gait, or gait rhythm may be indicative of one's health state. According to the system and method of the present invention, an individual carries a gait measurement sensor such as that described in Japanese Patent Application No. Toku 10-349748. The individual may carry the sensor on their belt or in their wallet. During his/her daily activities the sensor records the pressure changes and the frequency of one's walking movement as shown in Figs. 4 and 5 and as described by Hausdorff. This data can be downloaded daily to the analysis site at the person's convenience. Preferably the data is transmitted to the analysis site either by wireless transmission or via the remote computer and using a secured methodology or a combination of security methodologies, such as password protection, encryption of data, and the like. The data transfer can be via one of the many possible known techniques such as telephone lines, the Internet, intranet, cellular phone, palm pilot and the like. Fig. 6 shows one of the options of using the internet as a transfer media, where the individual first downloads the measured data to a computer via one of the ports, for example the infrared port. This allows the data in the sensor to be transferred to the computer and then to the analysis site. The analysis site (or any location the individual has designated for the analysis to be carried out) will synchronize the new data with the existing data. If the individual is interested in an analysis, he/she can start the analysis on-line (this procedure can also be automated as desired). The

results may be displayed as shown in Fig. 7. In this example, the data is compared against data from persons in other age groups to indicate the relative health condition of the individual, and is displayed as a range or index between 0 and 1 as shown in Fig. 7. The range or index is developed by analyzing data from a number of individuals to determine what is an average range for persons in general good health. The same data may be collected from persons with known health diseases or problems and the averages determined in order to set an upper bound. In Fig. 7 the data is shown over some period of time, and in general the data slopes upward with time indicating that the actual values change as an individual ages, but the absolute range may stay somewhat constant. The data may be grouped in many categories. For example, indexes may be calculated for individuals of the same age group or of the same gender. Indexes may be calculated for individuals that live in a certain geological area, just to name a few. Further, as illustrated in Fig. 8, an individual may analyze and display their data to show the effect aging is having on that person, in other words whether the person is aging at a "normal" rate in comparison to others. The term "aging" as used herein means a deterioration in one's physiological characteristics. Fig. 8 displays this data again in the form of a range or index over time. Alternatively, the data may be displayed as shown in Fig 9 which shows a slow, gradual decline in the health index over time. A small slope of the line in Fig. 9 indicates that the person is aging slowly or that their physiological characteristics are changing slowly. The greater the slope of the line, the faster the person is "aging", or in other words the faster the physiological characteristics are deteriorating. A sudden deterioration, as shown in Fig 10 where there is a sudden change in the slope of the line, indicates a serious health problem since the person's health condition is deteriorating sharply. This information may prove very valuable to the person since such a deterioration may occur before the person feels that something is wrong. The system can analyze the signals and detect changes, where the human eye and feeling cannot detect. An analytic result such as that shown in Fig. 10 would prompt the person to seek medical attention. This ability of preventative health care is one of the key aspects of this invention.

Of course, the system and method of the present invention may be employed for an individual to obtain information regarding many other physiological

characteristics such as heartbeat data, blood pressure data, etc. The analysis selected by the individual may be able to indicate whether the corresponding part of the organ is function normally or under some heavy loading or abnormal condition. This information is extremely valuable for the individual to monitor their health condition.

Moreover, the system and method of the present invention can employ known analysis techniques that can analyze various types of data simultaneously. In so doing, an individual may obtain information about additional functions of their body, and in some cases using only one type of data. This ability not only allows one to narrow down a symptom(s). This ability is also a major enhancement of the prevention ability aspect of the present invention. This type of total diagnosis of the human body will in turn help the physician to gain focus on the problem easier and more directly. As described, if an individual uses the system frequently, the system and method of the present invention can provide valuable data and can give a warning signal to the individual for changes in their health condition. It is well known in the medical profession that the earlier one can diagnose a problem and begin a treatment, the easier and better chances that we can cure the disease. This kind of individualized healthcare profiling system can potentially save many lives and great national expenses on healthcare, as we will be able to detect abnormal conditions in advance.

In another example, the system and method of the present invention may be used to obtain and monitor information about ones heartbeat. It has been proposed by Ivanov, P.Ch. et al. in "Multifractality in Human Heartbeat Dynamics"; Nature; Vol. 399, pp. 461-465 (June 1999) the entire article of which is hereby incorporated by reference herein, that analysis of biomedical signals, in particular heartbeats, can detect serious heart disease, such as congestive heart failure.

Further, as described by Peng, C.K. in "Long-Range Anticorrelations and Non-Gaussian Behavior of the Heartbeat", Physical Review Letters, Vo. 70, No. 9, pp. 1343-1346 (1993), the entire article of which is hereby incorporated by referenced herein. Figures 11a and 11b show two different heartbeat signals at extreme ends i.e. Fig. 11a, being a very healthy heart and Fig. 11b being a very sick heart. Although when the signals are plotted in this manner, it is clear they are very

different, without any medical training it is very difficult for a person to point out which one is a healthy heartbeat and which one is from a heart with disease. This is even more unclear if a heart is functioning at diminished health, but is not yet diseased. Moreover, rather than using solely observation and experience to
5 determine the relatively healthiness of the hearts, it would be highly desirable to have an algorithm and scientific method for comparing the hearts. (Note, we are not suggesting that the present invention be used to replace medical expertise. However, we are suggesting that the present invention provides an additional tool for society and it is easy enough for use by the general public.

10 Using the system and method of the present invention, individuals with the heartbeat signals shown in Fig. 11a and Fig. 11b can download their heartbeat data to the analysis site and one of the possible display of analytical results they may select is graphical and is shown in Figure 12. In Figure 12, Line 1 indicates a healthy heart and Line 2 indicates a heart with disease. Another alternative is to
15 provide the individuals with a number alpha (α). Algorithms can be used to calculate α (see Peng, et al.) from the heartbeat data. If α is equal 0 you have a healthy heart. If α is equal to 0.5 you have a diseased heart. Of course, the value of α may fall anywhere between 0 and 0.5.

Of significant advantage, the system and method of the present invention
20 provides a powerful monitoring and early warning tool. It is most likely that a heart is not going to change from healthy to sick, instantly. This means that a unhealthy heart goes through a deterioration period. Using this system and method of the present invention, we would be able to indicate to the individual the change in the value α of their heart over time. Consequently, the individual is alerted to the
25 possibility of a disease that may be damaging his/her heart well before he or she notices it.

In another example, the system and method of the present invention may be employed by an individual to obtain information representative of the quality of that person's sleep, and the possibility that the person is experiencing sleep apnea. It has
30 been proposed by Ivanov, P.Ch, et al. in "Scaling and Universality in Heart Rate Variability Distribution"; Physica A, 249, pp. 587-593 (1998), the entire article of which is hereby incorporated by reference herein, that analysis of beat to beat heart

rate intervals can show evidence of sleep apnea.

Thus, according to the system and method of the present invention, an individual can obtain information regarding their sleep patterns by wearing a sensor suitable for collecting and storing heartbeat intervals and frequency signals while sleeping. Preferably, after each night's sleep the individual transmits the data to the analysis site (or to an authorized third party) as described above. The analysis site is configured to analyze the data using known wavelet and Hilbert transform analysis as described in detail in Ivanov, et. The present invention offers the individual a powerful tool to obtain very valuable health information about themselves, and to provide long term monitoring of one's health. In the past, obtaining information about sleep apnea required lengthy tests, often performed overnight in sleep labs. Of significant advantage, the present invention allows an individual to direct the application of the latest scientific developments to their own physiological data to obtain detailed, personalized information about their state of health. Such a personalized system and method offers the individual a very powerful tool which has never before been possible.

Moreover, the benefits of the present invention are greater reaching than just for the individual. As described above, the benefits of preventative medicine and early diagnosis and treatment can save millions of dollars. In another example, public safety can be enhanced as in the case where sleep apnea can be monitored for those individuals whose jobs impact public safety, such as pilots, drivers, doctors, plant operators and the like, who if unable to stay awake could cause serious accidents. Early detection and monitoring of sleep apnea for such individuals could lead to treatment before a problem occurred.

In summary, a system and method for obtaining information about one's health state is provided by the present invention. As described above, signals which can be measured in this invention are both involuntary physiological characteristics or rhythms such as heartbeat, pulse, electrocardiogram, body temperature, brain pulse, breathing and the like, and voluntary physiological characteristics or rhythms such as gait, stepping, finger tapping, clapping, chewing, blinking and the like. Each signal is measured as an output of internal function which are generated in response to complex relationships among the whole body such as the brain, neural

network, heart, lung, kidney and so on. The present invention puts into the hands of the individual a powerful tool to obtain information about their own state of health that before now has not been available to a person in their everyday life. The benefits of such a tool are wide spread. Such information can be used for preventive purposes. It can be used to assist and evaluate physical fitness programs. It can be used as an early warning system of the onset of certain diseases. Just the knowledge regarding one's heart functioning, can save lives and millions of dollars in emergency medical costs by providing persons with an easy, noninvasive way to detect when they might be at risk of a heart problem based on a change in their data. Monitoring one's physiological characteristics can lead to changes in one's lifestyle habits to promote health. Having such detailed data about one's health state can be a very persuasive motivator. The benefits of such a system and method are vast. Employers and health organizations could find such a system useful in reducing medical costs of its employees/members.

As taught by the foregoing description and examples, a personalized health profiling method and system are provided by the present invention. The foregoing description of specific embodiments and examples of the invention have been presented for the purpose of illustration and description, and although the invention has been illustrated by certain of the preceding examples, it is not to be construed as being limited thereby. They are not intended to be exhaustive or to limit the invention to the precise forms disclosed, and obviously many modifications, embodiments, and variations are possible in light of the above teaching. It is intended that the scope of the invention encompass the generic area as herein disclosed, and by the claims appended hereto and their equivalents.

I Claim:

1. A method of providing information regarding the health of individuals, comprising the steps of:
 - 5 collecting data representing one or more physiological characteristics of an individual over a period of time;
 - inputting said data into a computer environment, said computer environment including an analysis site configured at least in part for analyzing said data and producing one or more desired analytical results representative of the one or more
 - 10 physiological characteristics and wherein the results are selected by said individual; and
 - outputting said desired analytical result to the individual.
2. The method of claim 1 wherein said desired analytical result is a
- 15 graphical representation.
3. The method of claim 1 wherein said desired analytical result is a numerical representation.
4. The method of claim 1 wherein said analysis site is further
- 20 configured to compare said data to previously stored data representing data collected at another period of time, and wherein said desired analytical result is a comparison of the data collected at the two periods of time.
5. The method of claim 1 wherein the data is a signal representative of a
- 25 subconscious or involuntary physiological characteristic of the individual.
6. The method of claim 1 wherein the data is a signal representative of a conscious or voluntary physiological characteristic of the individual.
7. The method of claim 1 wherein said data is a signal representative of
- 30 the rate of an individual's heartbeat.

8. The method of claim 1 wherein said data is a signal representative of the frequency and amplitude of an individual's heartbeat.

5 9. The method of claim 1 wherein said data is a signal representative of an individual's gait

10. The method of claim 1 wherein said data collection occurs during the individual's normal daily activity.

10 11. The method of claim 1 wherein said data collection occurs during exercise by the individual.

12. The method of claim 1 wherein said data collection occurs during sleep of the individual.

15 13. The method of claim 1 wherein the desired analytical result is outputted to any one of or any combination of: the individual, a medical doctor, a medical professional, an insurer, a hospital, healthcare maintenance organization, or other authorized third party.

20 14. A system for profiling the health of an individual, comprising:
a sensor, worn proximate the body of the individual for collecting data representative of one or more physiological characteristics of the individual, said sensor having storage and at least one output;
25 a computer environment having an input and storage and being configured to receive the data from the sensor and to analyze the data to produce one or more analytical results selected by the individual.

30 15. The system of claim 14 wherein said computer environment includes a primary computer and one or more remote computers.

16. The system of claim 14 wherein said computer environment further

includes:

a primary computer;

an Internet server connected to the primary computer;

a computer network; and

5 one or more remote sites connected to the internet server via the computer network.

17. The system of claim 16 wherein said one or more remote sites are accessed by the individual or an authorized third party.

10

18. The method of claim 1 where in said collecting step, data is collected by a sensor worn proximate the body of said individual.

19. The method of claim 1 where in said inputting step, data is inputted into said computer environment by wireless transmission.

15

20. The method of claim 1 where in analyzing said data is preformed using any one, or a combination, of the analytical techniques selected from: statistical analysis, Fast Fourier Transformation (FFT), Detrended Fluctuation Analysis (DFA), Wavelet, Factual and Multi-fractal methods.

20

21. A method of providing information regarding the health of individuals, comprising the steps of:

25 collecting data by a sensor worn proximate the body of the individual, where the data represents one or more physiological characteristics of an individual over a period of time;

inputting said data into a computer environment by wireless or wired transmission, said computer environment including an analysis site;

30 analyzing said data using any one or, or a combination, of analytical techniques selected from: statistical analysis, Fast Fourier Transformation (FFT), Detrended Fluctuation Analysis (DFA), Wavelet, Factual and Multi-fractal methods,

to produce one or more desired analytical results representative of the one or more physiological characteristics; and

outputting said desired analytical results to a remote site.

- 5 22. The system of claim 14 wherein said sensor is comprised of a strain type acceleration sensor that detects pressure changes and frequency in acceleration and deceleration in the individuals gait rhythm during walking.
- 10 23. The system of claim 14 wherein said sensor includes a wrist band having a digital display.
24. The system of claim 14 wherein said sensor further includes:
storage means for storing said data collected by the sensor; and
15 output means for transmitting said data.
25. The system of claim 14 wherein said sensor further includes:
storage means for storing said data collected by the sensor;
output means for transmitting said data; and
20 analysis means configured to analyze said data.

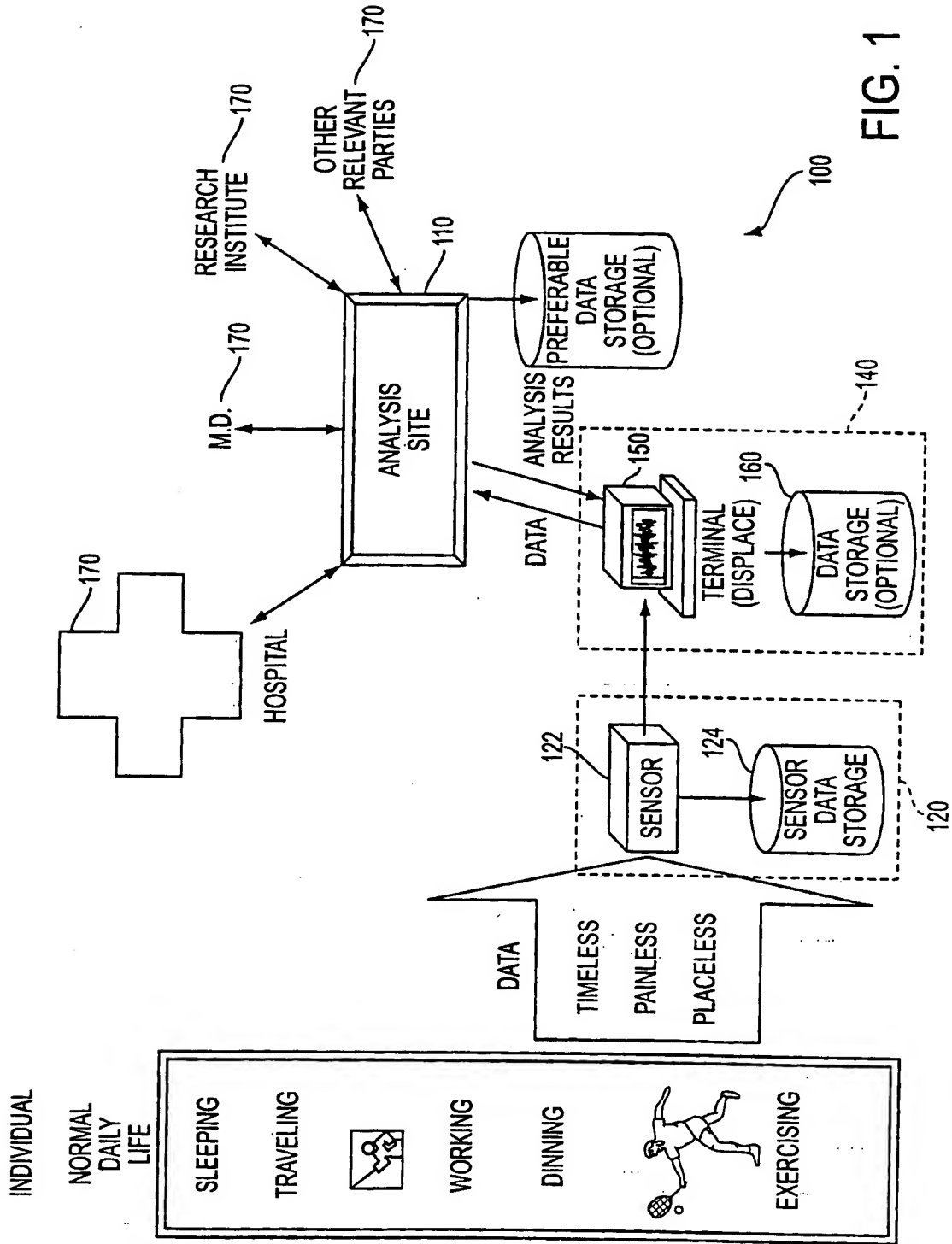
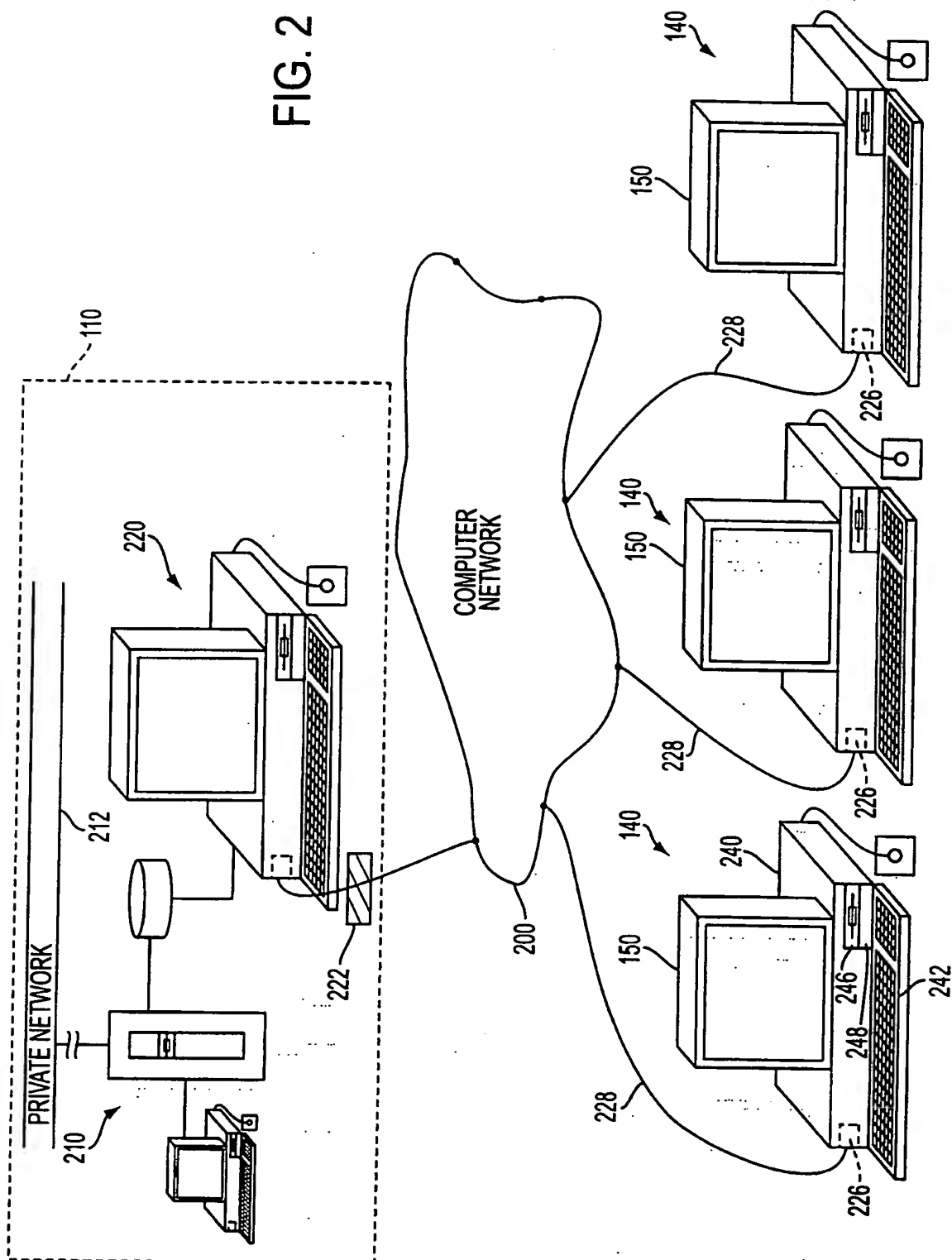


FIG. 2



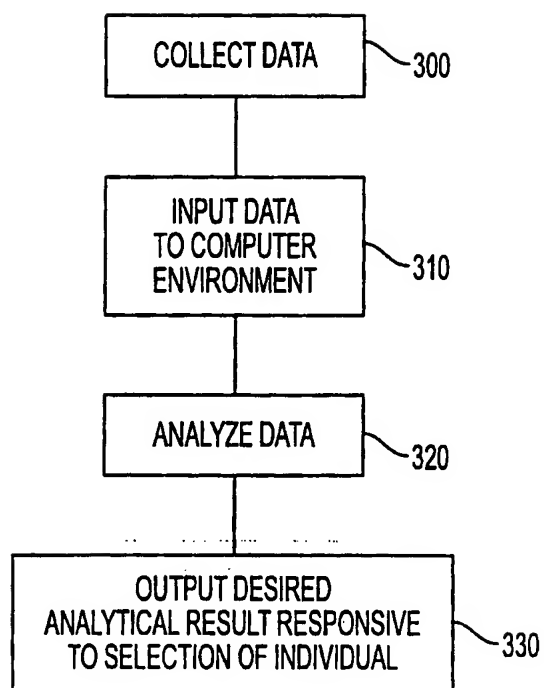


FIG. 3A

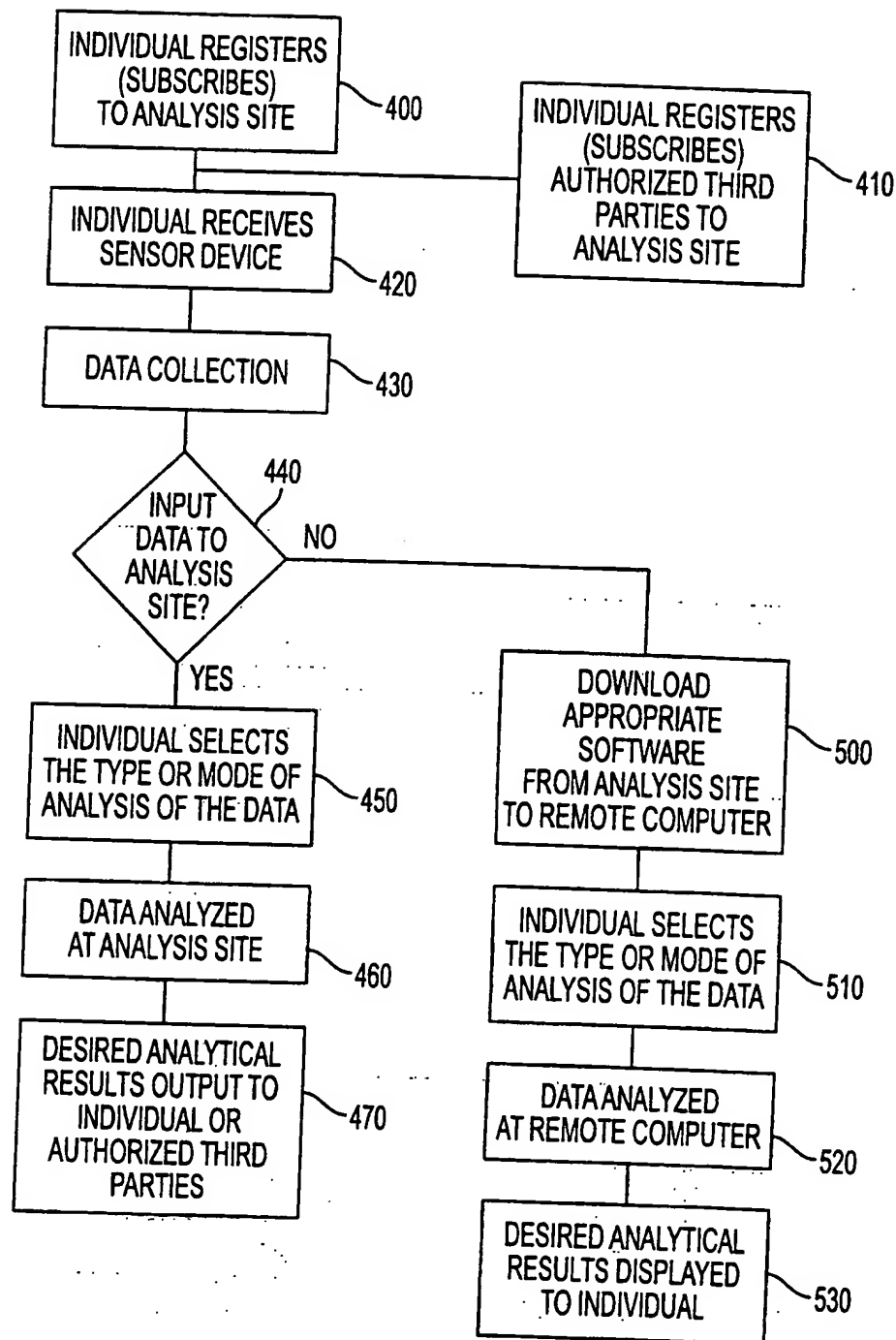
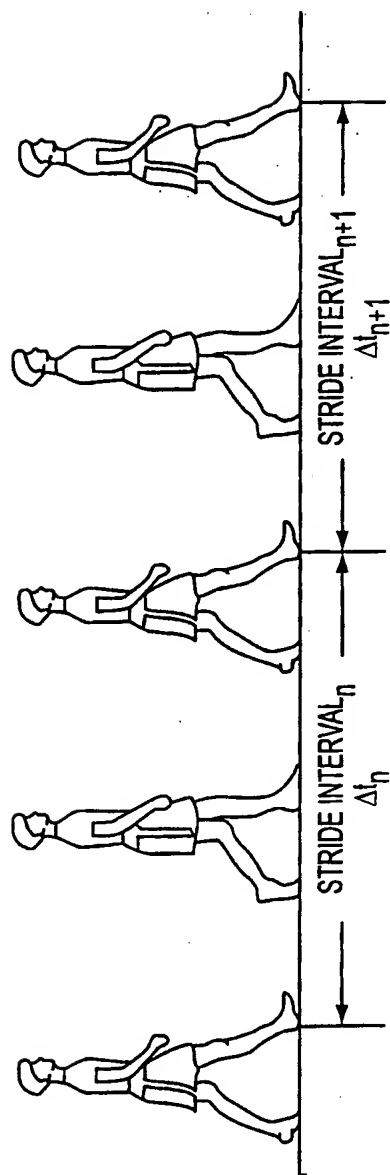


FIG. 3B



FLUCTUATIONS IN GAIT: RANDOM OR FRACTAL?

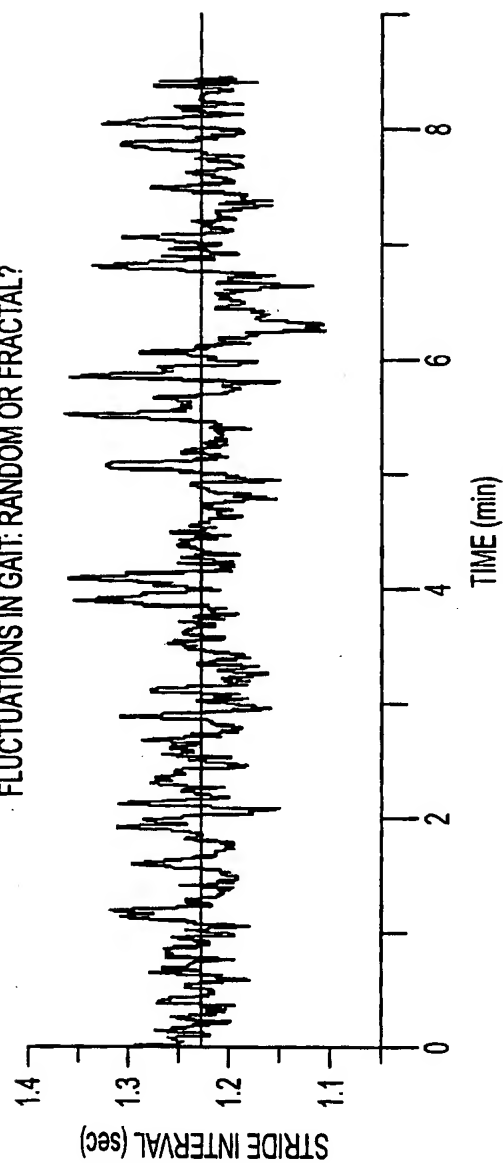


FIG. 4

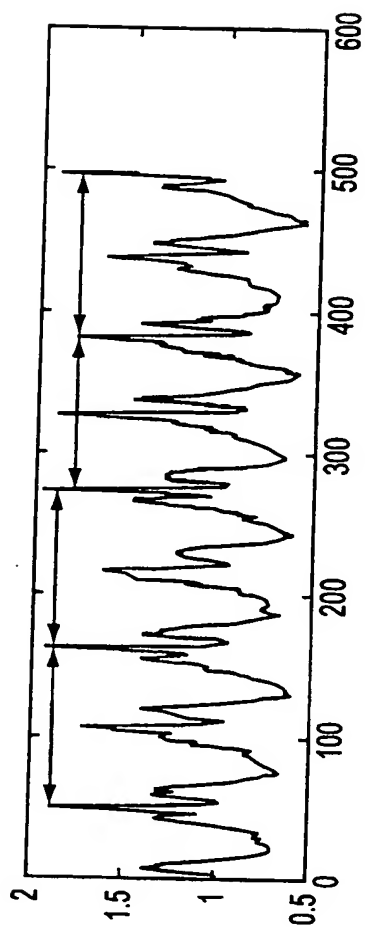


FIG. 5
PRIOR ART

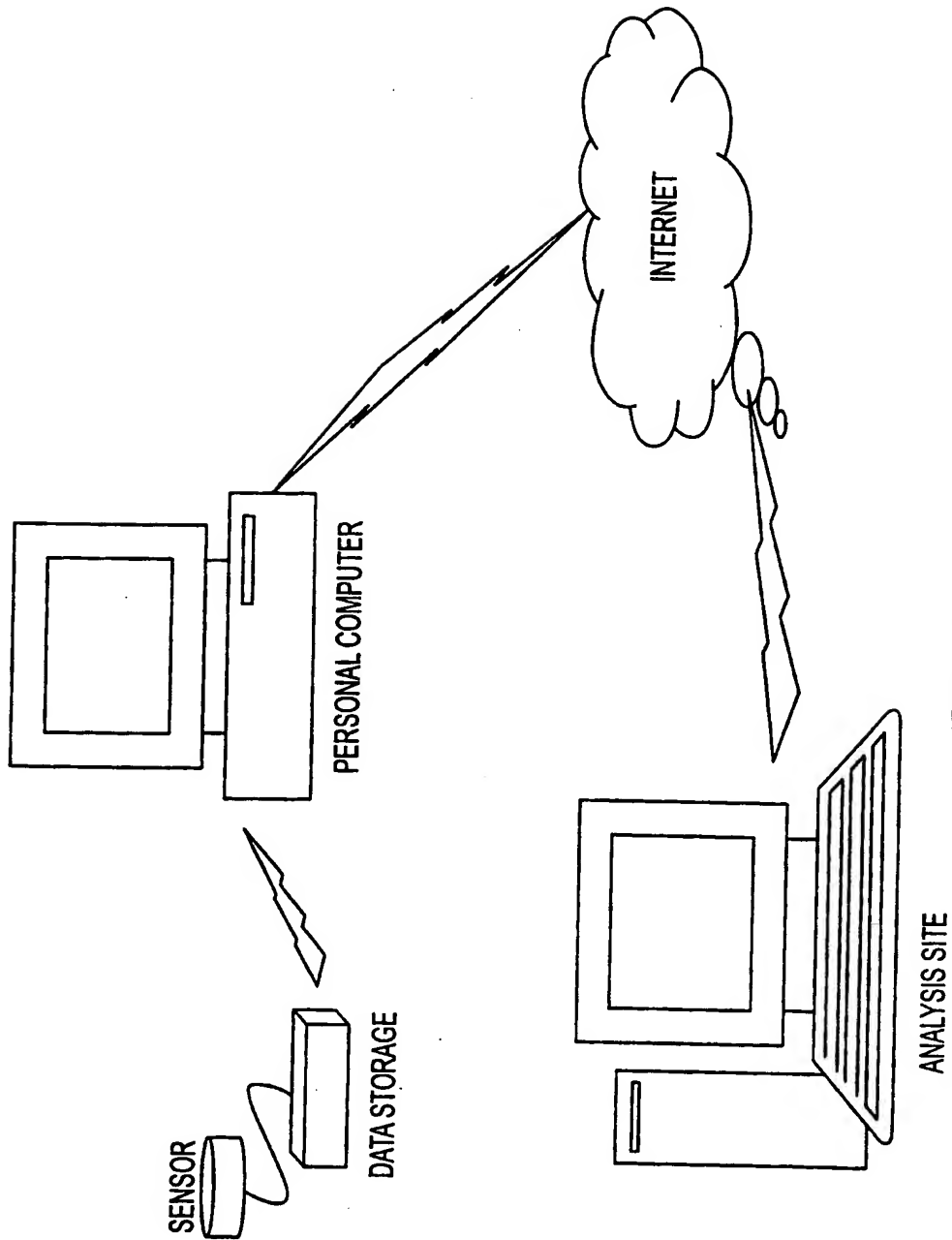


FIG. 6

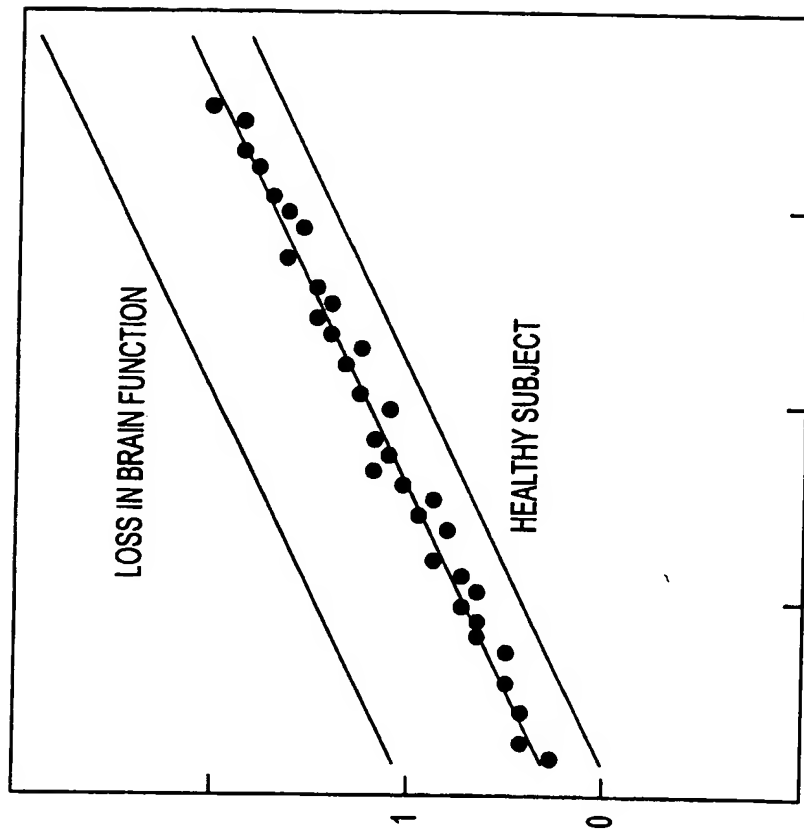


FIG. 7

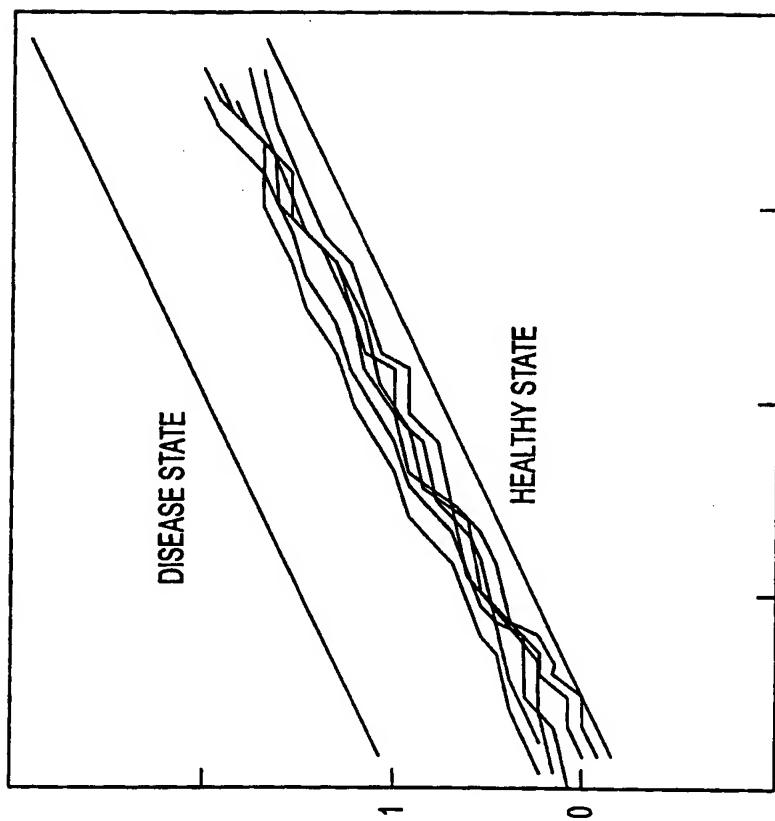


FIG. 8

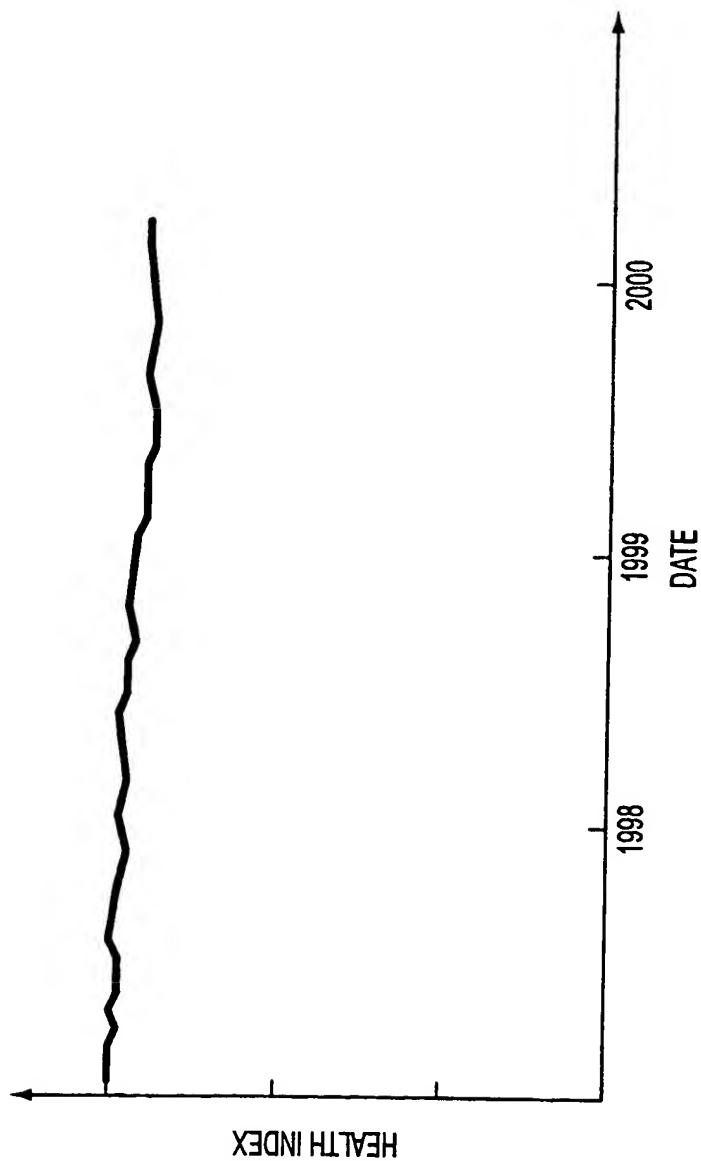


FIG. 9

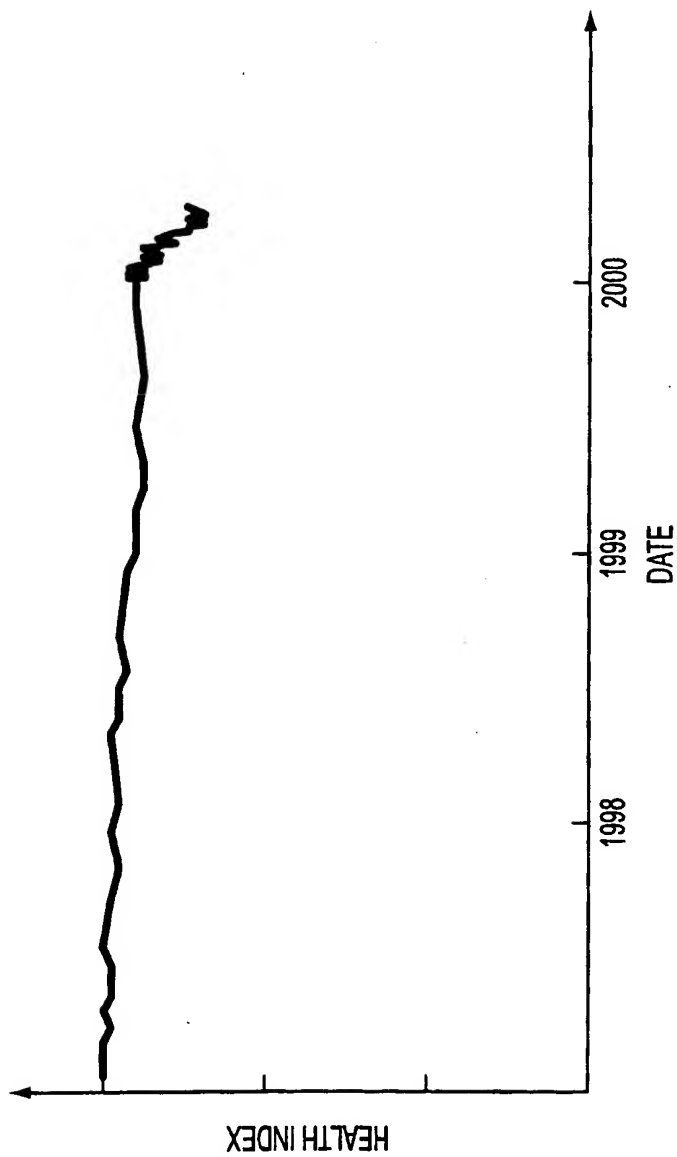
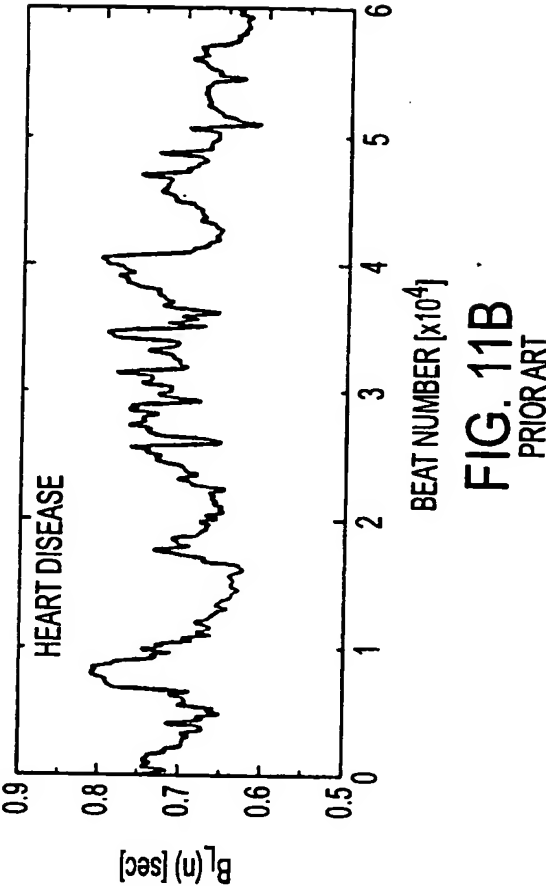
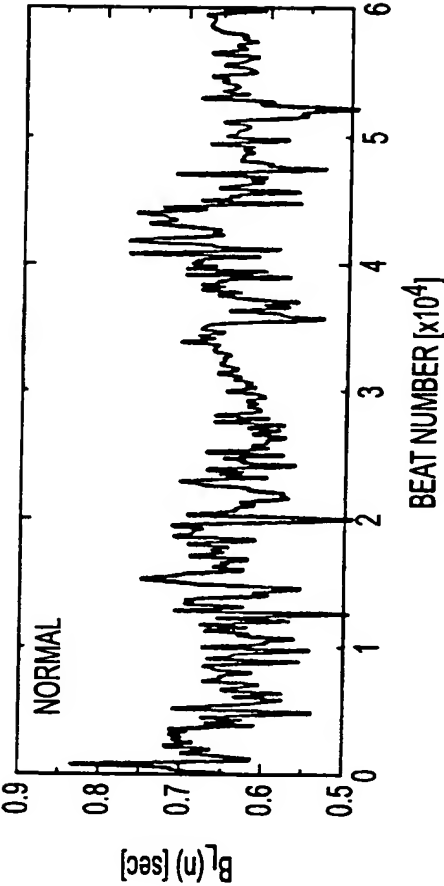


FIG. 10



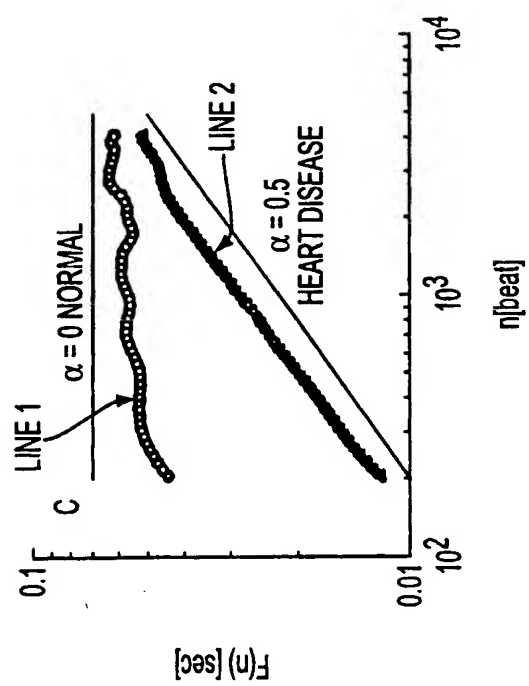


FIG. 12
PRIOR ART

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 September 2001 (27.09.2001)

PCT

(10) International Publication Number
WO 01/71636 A3

(51) International Patent Classification⁷: **G06F 19/00,**
A61B 5/00

(21) International Application Number: **PCT/IB01/00417**

(22) International Filing Date: **20 March 2001 (20.03.2001)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:
09/535,433 23 March 2000 (23.03.2000) US

(71) Applicant: **MITSUBISHI CHEMICAL CORPORATION [JP/JP];** 5-2 Marunouchi, 2-chome, Chiyoda-ku, Tokyo 100-0005 (JP).

(72) Inventor: **O'YOUNG, Lionel;** 575 Seastorm Drive, Redwood City, CA 94065 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

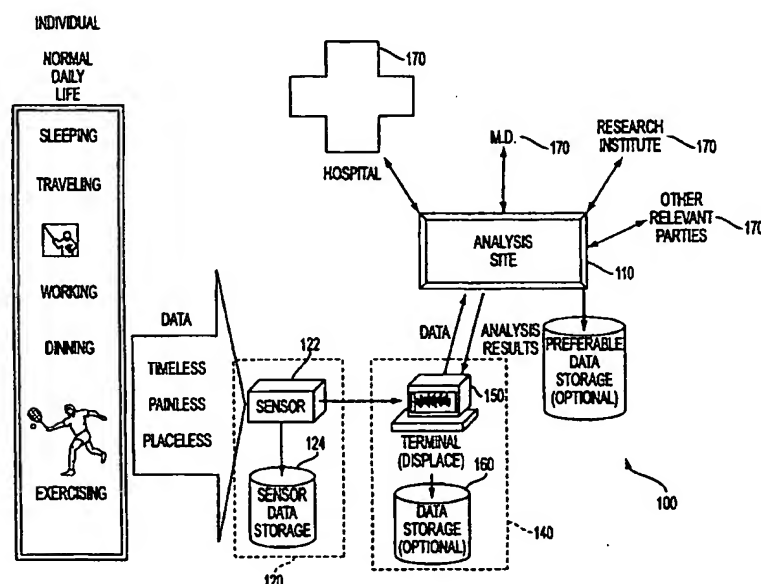
Published:

--- with international search report

(88) Date of publication of the international search report:
14 March 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **PERSONALIZED HEALTH PROFILING SYSTEM AND METHOD**



(57) Abstract: A system and method of allowing an individual to gain detailed information which is representative in part of their own personalized state of health or well being is disclosed. More specifically, in one aspect the present invention provides for collecting data representative of one or more physiological characteristics of an individual over time. The data can be temporarily or permanently stored in a collection device or sensor. The data is transmitted to a computer environment which includes an analysis site configured at least in part for analyzing the data and producing results representative of the one or more physiological characteristics.

WO 01/71636 A3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 01/00417

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G06F19/00 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 911 687 A (SANO KOICHI ET AL) 15 June 1999 (1999-06-15) column 6, line 20 - line 40 column 7, line 30 - line 37 claim 1	1-3,5,7, 8,10, 13-19, 24,25
X	WO 99 27842 A (BRAEUNING JOHANNES ;SCHUELLER STEFAN (DE); ORINCON CORP (US); VIRT) 10 June 1999 (1999-06-10) claim 1 --- -/-	1-5,10, 13-15, 18,24,25

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

17 October 2001

Date of mailing of the international search report

24/10/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Martelli, L

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 01/00417

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 891 060 A (TRIANO JOHN J ET AL) 6 April 1999 (1999-04-06) column 7, line 3 - line 31... column 9, line 52 -column 10, line 21	1-4,6, 10,11, 13-18, 24,25
X	EP 0 974 304 A (DIMPFL WILFRIED PROF DR) 26 January 2000 (2000-01-26) abstract	1-3,6, 12-14, 18,20, 21,24,25

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 01/00417

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5911687	A	15-06-1999	JP 9135816 A	27-05-1997
WO 9927842	A	10-06-1999	US 6027217 A	22-02-2000
			WO 9927841 A1	10-06-1999
			WO 9927842 A1	10-06-1999
			US 6033076 A	07-03-2000
US 5891060	A	06-04-1999	NONE	
EP 0974304	A	26-01-2000	AU 5412699 A	14-02-2000
			DE 29918193 U1	24-02-2000
			WO 0004827 A1	03-02-2000
			EP 0974304 A1	26-01-2000
			EP 1098593 A1	16-05-2001
			US 6157857 A	05-12-2000